EXHIBIT 601

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
IN RE: DIGITEK PRODUCT LIABILITY
LITIGATION
THIS DOCUMENT RELATES ONLY TO:
Kathy McCornack, an individual;) MDL No. 2:09-CV-0671 Daniel E. McCornack, Jr., an) individual; and Ralph J.) McCornack, a minor by and) through his guardian ad litem,
Plaintiffs,
V .)
Actavis Totowa, LLC, et al.,
Defendants.)
DEPOSITION OF GORDON LEMM, M.D.,
Friday, October 2, 2009
Templeton, California
9.55 a.m 12.35 p.m.
REPORTED BY CINDY D. GRIFFITH CSR #7281

Cleveland 216.523.1313

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1
            THE DEPOSITION OF GORDON LEMM, M.D.,
 2
   was taken at the offices of GORDON LEMM, M.D., 292
   Posada Lane, Suite D, Templeton, California, before
 3
   Cindy D. Griffith, a Certified Shorthand Reporter in and
 4
 5
   for the State of California, on Friday, October 2, 2009,
    commencing at the hour of 9:55 a.m.
 6
 7
   APPEARANCES OF COUNSEL:
 8
 9
   FOR PLAINTIFFS:
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    FOR DEFENDANT ACTAVIS INC., ACTAVIS ELIZABETH LLC, AND
14
   ACTAVIS TOTOWA LLC:
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19
    FOR DEFENDANT MYLAN PHARMACEUTICALS INC., MYLAN BERTEK
20
    PHARMACEUTICALS INC. AND UDL LABORATORIES, INC:
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                        adonahue@shb_com
25
```

1		I N D E X		
2	WITNESS	EXAMINATION BY	PAGE	
3	Gordon Lemm, M.D.	Mr. Moriarty	4, 95	
4		Mr. Ernst	8 9	
5				
6		EXHIBITS		
7	FOR THE Defendants PAGE			
8	1 Curriculum Vitae	2	5	
9	2 Article		14	
10	3 Section of PDR r	re Lanoxin	17	
11	4 Digitek package	insert	18	
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15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				

3

1		Gordon Lemm,	
2	having been first duly sworn, was		
3	examined and testified as follows:		
4			
5	EXAMINATION		
6			
7	BY MR. MORIARTY:		
8	Q	Tell us your full name, please.	
9	А	Gordon Dean Lemm, L-E-M-M.	
10	Q	And you are a medical doctor; correct?	
11	А	Yes.	
12	Q	Have you ever had your deposition taken before?	
13	А	Yes, I have.	
14	Q	How many times?	
15	А	Three or four.	
16	Q	Were those in personal injury cases or medical	
17	negligence cases? Could be other things, too. Those		
18	popped to mind.		
19	А	Yeah. One was an injury injury case. I	
20	think one was a negligent case.		
21	Q	Okay. Have you ever been sued for medical	
22	negligence?		
23	А	Um, I was named in a suit and it was dropped.	
24	Q	All right. So, this deposition is not going to	
25	be signi	ficantly different from those prior depositions.	

```
1
    Might be a little longer, but I'm going to ask you
 2
    questions in plain English. I need plain English
    responses. Okay?
 3
        Α
 4
             Okay.
 5
             Court reporters don't understand nods, shakes,
    hand gestures or uh-huhs and huh-uhs. Okay?
 6
 7
             Understand.
        Α
             We should not talk over one another because
 8
 9
    that also makes it difficult for her. Okay?
             (Witness nods head up and down ...)
10
11
             And if I ask you something that you just don't
12
    understand, tell me and I'll try to make it clear to
13
    you. All right?
14
        Α
             Okay.
15
             And if at any point I ask you a question and
16
    you want to refer to your medical records, please feel
17
    free to do that. Okay?
18
        Α
             Okay.
19
             I don't want you to guess.
20
        Α
             All right.
              (Defendants' Exhibit 1 was marked for
21
              identification.)
22
    BY MR. MORIARTY:
2.3
24
             I asked for a copy of your C.V. and you did,
25
    indeed, produce Exhibit 1; correct?
```

1	А	Yes.		
2	Q	Is this something that you routinely keep?		
3	А	Yes, it is.		
4	Q	How old are you, by the way?		
5	А	I'm 56.		
6	Q	And you got your we overlapped in		
7	Washington, D.C.			
8	А	Great.		
9	Q	I was an undergrad at Georgetown while you were		
10	getting your M.D. degree at G.W.			
11		Did you do a subspeciality residency?		
12	А	Yes, family practice.		
13	Q	Where?		
14	А	In Ventura County Medical Center.		
15	Q	Are you board certified?		
16	А	Yes.		
17	Q	Have you been recertified continuously?		
18	А	Yes.		
19	Q	And still are today?		
20	А	Yes.		
21	Q	And I assume that you're licensed to practice		
22	medicine	at least in the State of California?		
23	А	Correct.		
24	Q	Any other states or		
25	А	No other states. I do have a second board		

```
1
    certification, and that's in emergency medicine. But I
 2
   am not actively practicing emergency medicine.
             Not even moonlighting?
 3
        Α
 4
             Correct
 5
             When was the last time you did any emergency
   medicine?
 6
 7
             Approximately 18 years ago.
             And I do not see on your C.V. any publications.
 8
 9
             Correct.
             Do you have any publications in the medical
10
11
   literature?
12
        Α
             No.
13
        Q
             Do you have any teaching appointments?
14
        Α
             Um, no, not currently.
15
             Do you -- when was the last time you had a
16
    teaching appointment?
17
             When I was the assistant director of the
18
    emergency department of Ventura County Medical Center,
   and I left there in 1989.
19
20
             Do you do any research?
        Α
21
             No.
             Do you subscribe to or regularly review any
22
23
   particular medical journals, whether in hard copy or on
24
   line?
25
             I routinely review the American Medical
```

1 Association Journal and the Journal of Family Practice. 2 Anything else? No. 3 Α Do you have any expertise in toxicology? 4 5 Α No. 6 0 Pharmacokinetics? 7 Α No. Pharmacology? 8 9 Α No. What percentage of your practice is pediatrics? 10 Q 11 Α About 10 percent. What percent involves cardiology issues? 12 0 13 Α Probably about 30 percent. 14 When you have patients with heart disease of 15 one sort or another, do you typically refer them to a 16 cardiologist? 17 Α Yes. 18 And then, as the patient is going on in their 19 course of treatment, you might continue to prescribe 20 certain cardiac medications that have been prescribed by a cardiologist; correct? 21 22 Correct. Α 23 Are you, at that point, comanaging with the 24 cardiologist? 25 Α Yes.

1 So, in this particular case of 2 Daniel McCornack, were you, in your mind, comanaging his atrial fibrillation with Dr. Von Dollen? 3 Α Yes. 4 5 Do you know Dr. Von Dollen? Α Very well. 6 7 I assume you remember Dan McCornack? 8 Very well, yes. 9 Are any of the other members of the McCornack family patients of yours? 10 11 Α Yes, they are. 12 And, obviously, I don't want to get into any 13 questions about what you're treating them for, but I just want to know what members of the McCornack family 14 15 are patients of yours. 16 His wife and two sons. 17 And in the one year -- I'm sorry, I'm going to 18 take a step back. 19 Do you do any psychiatry? 20 Um, I would do typical psychiatry that would be done by most family practice doctors. 21 22 You might prescribe an antidepressant or 2.3 something like that? 24 Α Correct. 25 Dan McCornack died in late March 2008; right? Q

1 Correct. 2 How many times have you seen his wife since 3 then, as a patient? Two, maybe three times. 4 Α 5 0 Have you seen her for any other reason besides being a patient? 6 7 Α No. Let's talk about what you may have reviewed to 8 prepare for today. In front of you you have your medical chart; correct? 10 11 Α Correct. 12 And did you review it to prepare for today? 13 Α Yes, I have. 14 And did you review anything outside of the 15 medical chart to prepare for today? 16 I reviewed some literature regarding digoxin. 17 I reviewed a pharmacology textbook, Goodman and 18 Gilman, and I reviewed the PDR. And I also reviewed, 19 this morning, one article regarding digoxin levels. 20 All right. First of all, do you know what edition of Goodman and Gilman? 21 No, I don't. It's an old edition. It's one I 22 2.3 had from medical school. 24 Do you have it here at the office? 25 Α I do.

1 And you reviewed the PDR? 2 Α Uh-huh. Which version? 3 Q 4 It would have been the -- this last year. 5 0 Were you looking at the Lanoxin label or a 6 Digitek label? 7 Lanoxin. Α 8 Is that PDR here in this facility? 9 Α Yes, it is. You said you reviewed an article about levels? 10 Q 11 Α Yes, digoxin levels. What article was that? 12 0 13 Α It's an article that was faxed to me by Mr. Ernst. 14 15 And what's the title? Who are the authors, if 16 you know? I don't know offhand. 17 18 Is it here? 19 Yes, it is. 20 And what else did you review? Anything -- any other literature besides the article that he faxed you, 21 the PDR or Goodman and Gilman's? 22 2.3 Α No. 24 Now, also in your medical record that is not in 25 the copy that I have secured from a medical records

```
1
   service is a fax -- what looks like a fax transmittal
 2
   letter dated yesterday.
 3
        Α
             Right, uh-huh.
             And attached -- it's from Mr. Ernst's office;
 4
 5
    correct?
 6
        Α
             Yes.
 7
             And attached to that is -- is this what was
   faxed?
 9
        Α
             Yes, it is. Yeah.
             I'll try to figure that out if you want, Don.
10
        Q
11
             MR. ERNST:
                        Huh.
   BY MR. MORIARTY:
12
13
        Q
             Looks like 9:09 a.m.?
14
        Α
             Uh-huh, correct.
15
             And attached to it is the death investigation
16
    report by the Santa Cruz County Sheriff's office; right?
17
             Right.
        Α
18
             Three pages?
             Uh-huh.
19
        Α
20
             Then there's an autopsy report?
        0
             Right.
21
        Α
22
             And this autopsy report has "Cause of death,
2.3
    cardiac arrest due to ventricular arrhythmia, due to
24
   atrial fibrillation, due to hypertensive and
25
   arteriosclerotic cardiovascular disease."
```

1 Do you see that? 2 Α Yes. And this is Dr. Mason's autopsy report, is it 3 Q not? 4 5 Correct. Α Now, since you received that fax, have you seen 6 7 any amended or updated death certificates or autopsy reports? 9 Α Yes. Mr. Ernst showed me one this morning. All right. We'll get into that. 10 0 11 Did he show you anything else this morning? Um, I think that was it. That report and the 12 Α 13 article that was faxed over regarding digoxin levels. 14 Have you seen any lab reports from NMS Labs of 15 Pennsylvania? 16 If it that's referring to the toxicology 17 report, yes. 18 When did you first see the toxicology report? 19 This morning. 20 0 Never before this morning? Α Correct. 21 Mr. Ernst had five or six, I can't tell from 22 23 the reports, of Mr. McCornack's Digitek tablets tested 24 for potency at NMS Labs. I want you to assume that. 25 Okay?

```
1
        Α
             Okay.
 2
             Have you seen the results of those tablet
   tests?
 3
             No, I have not
 4
 5
             So you don't know today whether those tablets
   were within the specification ranges of the .250 label
 6
 7
   Digitek dose?
 8
             I do not know.
 9
             All right. I'd like to take a two-minute
   break, and if you could bring in the Goodman and Gilman
10
11
   and the article, I'd appreciate it.
12
               (Pause in the proceedings.)
13
             MR. MORIARTY: You could mark that as Exhibit
   2, please.
14
              (Defendants' Exhibit 2 was marked for
15
16
              identification )
17
             MR. ERNST: You've handed me a document which
18
   appears to be a packet insert.
             MR. MORIARTY: I'll cover it all on the record.
19
20
    Fear not.
             MR. ERNST: Is the print made small to just
21
22
   hurt guys like me who have trouble reading? A little
23
   humor.
24
             MR. MORIARTY: Do you have bifocals?
25
             MR. ERNST: No.
```

```
MR. MORIARTY: Wait until you get to my age,
 1
 2
   man.
             Handing you what's been marked as Exhibit 2,
 3
   is that the article that Mr. Ernst sent to you or
 4
 5
   brought to you, about levels?
        Α
             Yes, correct.
 6
             Have you ever done any other independent
 7
 8
   research about the postmortem redistribution of
 9
   digoxin?
        Α
             No.
10
11
        0
             Do you know how many articles there are besides
12
    this one about postmortem redistribution of digoxin?
13
        Α
             No.
14
             Before you -- did you read this article?
        Q
             Yes, I scanned it.
15
16
             Before reading that article, had you ever read
    anything about the postmortem redistribution of digoxin?
17
18
        Α
             No.
             Would it be fair for me to say that knowing
19
20
   what you do about the medical literature, would you
    suspect there's a lot more literature than this about
21
    the subject?
22
2.3
             I would expect so.
24
             This article is by Vorpahl and Coe in the
25
    Journal of Forensic Sciences in 1978; correct?
```

1 Correct. 2 This is about the time you were graduating from medical school; correct? 3 4 Α Correct. 5 Do you remember, as you were a resident and a medical student, what the state of the art was regarding 6 7 amino acids and testing for things like digoxin in blood and serum? 9 No, I don't recall anything specific. Okay. The summary at Page 333 of this article 10 11 that he gave you, first sentence says, "Postmortem serum 12 digoxin levels from any source routinely exceed 13 antemortem values." 14 Do you see that? 15 Correct. 16 Do you agree with that? 0 17 Α Uh-huh. 18 That's a "Yes"? 19 Α Yes. 20 And then, in the first sentence from the discussion section of this article, it says, "It is 21 22 clear from this investigation that postmortem digoxin 2.3 levels taken from cardiac blood, venus blood, or 24 vitreous humor do not mirror the antemortem levels." 25 Do you see that?

```
1
        Α
             Yes, I do.
 2
        Q
             Did I read it correctly?
 3
        Α
             Yes.
             Do you agree with it?
 4
 5
        Α
             Yes.
 6
             The next sentence says, "Substantial increases
 7
    in serum levels occur following death, irrespective of
    the source of the sample."
 9
             Did I read it correctly?
             Yes.
10
        Α
11
             Do you agree with it?
12
        Α
             Yes.
13
             Do you have any idea whether Dr. Mason, who
    amended his autopsy report just two days ago, ever read
14
    this article?
15
16
             I have no idea.
17
             Do you keep any toxicology texts in your home
18
   or office medical library?
19
             No, I don't.
20
             MR. MORIARTY: Could you please mark this as
   Exhibit 3.
21
              (Defendants' Exhibit 3 was marked for
22
23
              identification.)
24
   BY MR. MORIARTY:
25
             All right. I'm going to hand you what I've had
        Q
```

```
1
    marked as Exhibit 3. That is a photocopy that I made of
 2
    the PDR section concerning Lanoxin. I'm sorry, I can't
    remember what edition it was. But it was within the
 3
    last couple of years.
 4
 5
             Does that appear to be the same type of article
    that you reviewed --
 6
 7
        Α
             Yes.
             -- from your PDR?
 8
 9
        Α
             Yes.
             Hand that back, please. We'll get back to this
10
        0
11
    later.
12
        Α
             Okay.
13
              (Defendants' Exhibit 4 was marked for
              identification.)
14
    BY MR. MORIARTY:
15
16
             Exhibit 4, have you ever actually read a
    Digitek package insert?
17
18
        Α
             No.
19
             Do you know whether it contains the same
    information as the Lanoxin --
20
        Α
             I don't.
21
22
             -- package insert?
             I don't know.
23
        Α
24
             From your knowledge of the FDA and the way
25
    these things work, would the generic label tend to
```

```
1
   mirror the name brand level?
 2
        Α
             Yes.
 3
        Q
             We'll get back to that one, as well.
             I am looking at a book you brought in that's
 4
 5
    the Fifth Edition of Goodman and Gilman's
    Pharmacological Basis of Therapeutics; is that correct?
 6
 7
        Α
             Correct.
 8
             I notice that this is the 1975 version; right?
 9
             Yes.
             Probably got this as a medical student?
10
        0
11
        Α
             I did.
12
             When was the last time you read the chapter on
        0
13
    Digitalis and Allied Cardiac Glycosides?
             I reviewed it within the last few days.
14
        Α
15
             This book is highlighted. Do you know when it
16
   was highlighted?
17
             During medical school.
18
             MR. ERNST:
                        That's a great story.
19
             THE WITNESS: It's true.
20
             MR. MORIARTY: It's been around a long time.
21
             MR. ERNST: I have my law books. Do you have
22
   yours, Matthew?
2.3
             MR. MORIARTY: Not from law school. My law
24
   books from college.
25
             MR. ERNST: Alicia?
```

```
1
             MS. DONAHUE: I still have mine. Most of them,
 2
   anyway.
   BY MR. MORIARTY:
 3
             To cut to the chase, did you -- in reading this
 4
 5
    chapter recently, did you find anything about postmortem
    redistribution --
 6
 7
        Α
             No.
             -- in this?
 8
 9
             Did you look?
             No, I was not looking for that, but I don't
10
11
    recall seeing anything about that.
12
             Did you see anything in here about what
        0
13
    underlying anatomic or metabolic problems would increase
    the risk of digoxin toxicity?
14
15
             Yes. I do think some of that was covered in
16
    that text.
17
             Well, for example, it says here, "All digitalis
18
   preparations cause signs and symptoms of intoxication
19
   when given in high doses, " semicolon, "there is no
20
   nontoxic cardiac glycoside."
             Do you agree with that?
21
22
        Α
             Yes.
2.3
             And we'll get to this in more detail, but
24
   patients can manifest signs and symptoms of digoxin
25
    toxicity without taking excessive doses --
```

Gordon Lemm, MD

1 Α Correct. 2 0 -- isn't that true? 3 Α Yes. By the way, this book tends to use digitalis. 4 0 5 Is digoxin in the family of cardiac glycosides that are related to digitalis? 6 Yes, it is. 7 8 Okay. You get a free pass on this because I don't want to read it all. 10 Α Oh, my 11 So, Mr. Ernst arrived before Ms. Donahue and I 12 did today, did he not? 13 Α Yes, he did. 14 For how long did you talk before this 15 deposition today? 16 Approximately, um, 20, 30 minutes. 17 How many times before today have you met with 18 him or talked to him on the phone about Mr. McCornack's death? 19 20 I met with him once, and I've talked to him maybe a couple of times. 21 22 Has he retained you as an expert in this case? 23 Α I'm not sure, honestly. 24 Q Okay. Has he sent you any letters other than 25 what may appear in the medical folder that you have in

```
1
   front of you?
 2
             I think that's really been it.
             For the times that he has talked with you, did
 3
        0
   you bill him for that --
 4
 5
        Α
             Yes.
             -- for your professional time?
 6
 7
        Α
             Yes.
 8
             All right. Just like I'm going to be charged
 9
    today for this; right?
        Α
             Correct.
10
11
        0
             I was hoping you'd say no.
12
             I'm used to it
13
             Has he asked you to formulate any opinions
    about the cause of Mr. McCornack's death?
14
15
             Yes, he did when we first talked.
16
             When you first talked?
        Q
17
        Α
             Yes.
18
             And did you express to him an opinion about the
    cause of his -- Mr. McCornack's death?
19
20
        Α
             Yes, I did.
             When was this again? Just ballpark.
21
22
    I just need to know whether --
2.3
        Α
             Sure.
24
        Q
             -- it was in 2008 or 2000 --
25
             No, it's within the last couple of months.
        Α
```

1 And what did you tell him? 2 I told him that I thought I would be very suspicious that he died from digoxin toxicity. 3 Have you put that in writing anywhere? 4 5 Α No. You would be very suspicious that? 6 7 Α Yes. 8 But you didn't tell him that, to a reasonable degree of medical probability, that's what occurred? Α No. 10 11 0 All right. And we will explore this in much 12 greater detail later, but what was the basis for your 13 statement to Mr. Ernst that you would be very suspicious 14 that Mr. McCornack died of whatever you said, digoxin 15 something? 16 Um, based on the fact that it appeared that he died from a ventricular arrhythmia, there really wasn't 17 18 evidence that he had had a myocardial infarction or 19 anything else that had happened to him. I'd have to be 20 suspicious about the digoxin as being a cause for him having ventricular arrhythmia at his age. 21 22 Anything else? 2.3 I was aware of the fact that there were digoxin 24 pills out there that may have had a double dose, 25 accidentally, in the pills. And if he had that

1 medication, it would make me much more suspicious. 2 If he got double-dosed tablets? 3 Α Correct. Now, have you ever seen a double-sized digoxin 4 5 tablet? 6 Α No. 7 No patient has ever brought you one? 8 Α 9 Have you ever read about anybody who actually had one? 10 11 Α No. 12 So you're just basing it on the fact that there 13 was a recall; correct? 14 Α Correct. 15 Do you know anything about how many double-strength tablets were actually found, where they 16 were found, and whether any actually made it to the 17 18 marketplace? I have no idea. 19 20 Have you read the FDA's latest statement about 21 the remoteness, the remote chance that anyone got 22 defective Digitek and was harmed by it? 2.3 No, I have not. 24 I want to just take a little detour here, 25 because sometimes I like to do that.

1 Mr. McCornack, as of March of 2008, did he have 2 hypertension? Α Yes. 3 Did he have atrial fibrillation? 4 5 Α Intermittently, yes. 6 0 Did he have -- was he being treated for atrial fibrillation? 7 8 Α Yes. 9 He probably only had it intermittently because he was treated for it; right? 10 11 Α Correct. Was he obese? 12 13 Α Yes, he was somewhat overweight. Just because of his baseline medical 14 conditions, was he at risk for sudden cardiac death? 15 16 Yes, to some degree. 17 In a case of sudden cardiac death, if it's by 18 myocardial infarction, would the autopsy necessarily show an infarcted area? 19 20 It may not. Α So would it be fair for me to say that 21 Okav. there are a number of potential reasons why 22 23 Mr. McCornack might die of a sudden cardiac death, aside 24 from digoxin at all? 25 That's possible, yes. Α

1 Okay. He might die of a sudden cardiac death 2 aside from whatever dose of digoxin he took? Correct. 3 Α Have you discussed Dan McCornack's death or his 4 5 health condition with anyone other than his wife and Don Ernst? 6 7 Very briefly with Dr. Von Dollen. 8 When was that? 9 I probably have spoken with him on several occasions when Dan was alive, and then I believe I spoke 10 11 with him once after he died. Do you remember what the substance of the 12 13 discussion was in the postmortem discussion? 14 Um, whether he could have, you know, died from 15 digoxin toxicity or not. 16 Okay. Did Dr. Von Dollen express any opinions to you, to a reasonable medical probability? 17 18 Um, not really. It was more of a conversation 19 along the lines of the history of the digoxin toxicity, 20 just talking in general about that type of thing. In your career, how many times have you 21 22 diagnosed a patient with digoxin toxicity? 2.3 A quess on my part would be maybe ten times. 24 In those ten times, did you have clinical signs 25 and symptoms of digoxin toxicity?

Gordon Lemm, MD

1 Α Yes. 2 Did you have electrocardiographic signals of digoxin toxicity? 3 Α Yes. 4 5 Did you have elevated serum digoxin concentrations? 6 7 Α Yes. Have you ever rendered an opinion, by signing a 8 death certificate or otherwise, that a patient of yours died of digoxin toxicity? 10 11 Α No. Not even in the emergency room when you were an 12 13 E.R. guy? Not that I recall. 14 15 I assume that you keep up with your continuing 16 medical education? 17 Yes, I do. Α 18 When do you recall the last time you took any 19 CME regarding cardiac glycosides? 20 Α I don't recall any. Cardiac glycosides have been around and there's 21 so much published about them it's -- it's not a very 22 2.3 common topic at CME conferences is it? 24 Α Correct. 25 Are you a member of any medical societies or

1 associations? 2 Α Not presently. 3 What, in the past, were you a member of? American Board of Family Practitioners; The 4 Α 5 Academy of American Board of Practitioners. I didn't ask, but how long have you been 6 7 practicing in the Templeton area? 8 Twenty years. 9 Do you have any subspeciality training or expertise in nephrology? 10 11 Α No. 12 Do you have any military service? 13 Α No. 14 Have you ever written to a pharmaceutical 15 company to get more information about prescription 16 medication? Not that I recall. 17 Α 18 Do you know what an adverse event report is? 19 Α Yes. 20 If you are suspicious that a particular drug may have caused an adverse event in one of your 21 22 patients, have you ever made an adverse event report to 23 a pharmaceutical company? 24 Α Not that I recall. 25 Q I assume you did not make one in the case of

```
1
   Daniel McCornack; correct?
 2
        Α
             Correct.
             Do all prescription medications have risks?
 3
        Α
             Yes.
 4
 5
             And some have risks up to and including death,
   do they not?
 6
 7
             Definitely.
 8
             When you prescribe a medication for a patient,
 9
   are you making what is, in general, a risk/benefit
   analysis?
10
11
        Α
             Yes.
             So you conclude, if you're prescribing it, that
12
13
    the benefits outweigh the risks?
14
        Α
             Correct.
15
             When I -- how long has your office been in this
16
   building at 292 Posada Road?
17
             Nine years.
18
             I didn't notice that there was a pharmacy here
19
   in this building?
20
        Α
             There is not.
21
        0
             Is there a pharmacy on this street?
22
        Α
             No.
2.3
             And when you -- when a patient comes to see you
24
    in your office, do you have either physician assistants
25
   or medical assistants that see the patient first?
```

1 Α Yes. 2 Do they take a history? Yes, they take -- I have a medical assistant 3 who will take a brief history. 4 5 When you come in to ultimately see the patient, Q. do you confirm whatever history has been charted by the 6 7 medical assistant? Yes, I do. 8 9 Do you have any handouts that you give patients about atrial fibrillation? 10 11 Α No. If you are going to prescribe a drug like 12 13 diltiazem, or in his case I think the name brand was actually Dilacor, maybe -- I don't know, let me ask you: 14 15 Was Mr. McCornack getting a name brand like Dilacor or was he getting a generic diltiazem? 16 17 I don't know. I think he was getting the 18 generic. I don't recall that he needed or requested name brand. 19 20 Right. Did you have any discussions with Dan McCornack about the potential risks and 21 22 complications of diltiazem? 2.3 I don't recall anything specific. 24 Have you read the diltiazem label in the last 25 couple of years?

1 Α No. 2 Do you know from your memory whether it has potential cardiovascular risks? 3 Yes, it does. 4 Α 5 Does it have a similar risk profile to digoxin? Α I would expect so. 6 7 Did you ever have any explicit discussions with Mr. McCornack about the potential risks and 9 complications of taking a digoxin product? Yes, I believe I did. 10 11 0 When? I don't know. 12 13 Well, the first notes I see in your office records is back from 1994. Did you see him before then? 14 15 And there might be old records archived, or is that when 16 you started to see him? 17 That's when I first saw him. I saw him first 18 in 1994. 19 I, actually, have sort of scribbled out some 20 notes about how many times you saw him over the years. 21 Let's just basically say you saw him periodically from 1994 to the beginning of 2008; correct? 22 2.3 Α Correct. 24 Do you have any way of narrowing down for me 25 when it was that you may have seen -- I'm sorry, had

1 discussions with Dan McCornack about the potential risks 2 of digoxin? I don't think I could really narrow it down. 3 Α I count some 30 encounters with your office, 4 5 you or medical assistants. Some of them may have even been by phone. You're not able to give me any idea? 6 7 Although it's pretty routine for me to 8 discuss these kinds of things with patients. 9 Well, he was first prescribed a digoxin product 10 a number of years ago. 11 Α Correct. 12 Is it likely that you had those kind of 13 discussions with him at one of the first visits when he was getting this prescription? 14 15 It would be more likely than, yes. Is it your practice to periodically repeat 16 those sort of instructions if the patient continues on, 17 18 over time, with the prescription? 19 Α Yes, it is. 20 What would you routinely tell a patient about the potential risks and complications of digoxin 21 22 therapy? 2.3 I routinely tell them that they need to be 24 careful of problems regarding nausea, vomiting, 25 dizziness, low pulse rate. Those kinds of things.

1 In March of 2008, do you have any records in 2 your chart of having an office visit or a phone call from Dan McCornack or anyone in his family? 3 Α I'm sorry, when? 4 5 March of 2008. 0 6 Α I called his wife, Kathy, on 3-31-08. 7 That's after he was deceased? Q. After he died, correct. 8 9 0 I'm talking about when Dan was still alive. No, not in March. 10 Α 11 Q What about in February? 12 Α No. 13 0 Would it be your routine, if a patient called 14 complaining about something that might be a sign or 15 symptom of digoxin toxicity, for you to note it in your 16 chart? 17 Α Yes. 18 Would it be fair for me to assume, Dr. Lemm, 19 that Dan McCornack and none of his family reported any 20 signs or symptoms of digoxin toxicity to you in February or March of 2008? 2.1 2.2 Α Correct. 2.3 At his office visit in January of 2008, did he 24 report anything that looked to you to be suspicious of 25 digoxin toxicity?

1 Α No. 2 Did you even draw a serum digoxin concentration at that office visit in January of 2008? 3 No, not at that time. 4 5 When you order a set of basic chemistry studies, do you have like a menu or different studies 6 7 that you can choose from? Yes. There's a checkoff list with all of the 8 labs that we deal with. Do you individually have to check off things 10 11 like the BUN, creatinine, or is that part of a basic 12 panel? It's part of a panel. 13 14 All right. Chem 7 or Chem 12, whatever it 15 happens to be? 16 The one I typically use here, it's called a CMP 17 or complete metabolic panel. 18 Is the glomerular filtration rate typically 19 part of the basic metabolic panel at whatever lab you 20 use? 21 Yes. It's pretty routine. 22 Or is it a special checkoff? 23 With some of the labs it is automatic, and 24 others it would have to be a special checkoff. 25 Q The reason I ask is, in reviewing

1 Mr. McCornack's labs over the years, I don't think I 2 ever saw a GFR. Do you know why that would be? 3 Would not have been on that panel. All right. What happens to kidney function as 4 0 5 patients age? 6 Kidney functions slowly deteriorate. 7 Is GFR a measure of kidney function? 8 Yes, it is. 9 Is the BUN a measure of kidney function? 0 Yes, it is. 10 Α 11 0 Is the creatinine a measure of kidney function? 12 Α Yes. 13 0 What is uric acid a measure of? Uric acid is a measure of the uric acid in the 14 Α 15 It's typically used to look for gout. bloodstream. 16 Do you know what polypharmacy is? 17 Α Yes. 18 In patients who are taking a number of 19 medications, are they at more risk for adverse events related to medication? 20 Α 21 Yes. 22 0 Why? 2.3 Because those medications can affect kidney 24 function, liver function, excretion of medications. 25 There can be interactions among the medications.

1 Are you familiar with statistics on which drugs 2 lead to the highest rates of adverse drug events? Α No. 3 Are cardiac medications among the most 4 5 prescribed medications? 6 Α Yes. Would it surprise you that cardiac medications 7 8 are among the leaders in adverse drug events? 9 It wouldn't surprise me at all. And that would include digoxin? 10 0 11 Α Correct. If a patient has underlying renal 12 13 insufficiency, does it increase the risk of adverse reaction to a drug? 14 15 Α Yes. 16 Primarily cleared by the kidneys? 17 Α Yes. 18 Why don't you take a grab of the Digitek label 19 which I've marked as, what's that, Exhibit 4? Do I have 20 that right? Exhibit 4? Α 21 Yes. 22 MR. MORIARTY: And, Mr. Ernst, I did give you 23 one of those, did I not? 24 MR. ERNST: You did. 25 MR. MORIARTY: Being generous with my paper

```
1
          Yesterday I was very stingy.
 2
             MR. ERNST: You were very stingy yesterday. I
   meant to comment on that. You gave Alicia copies. You
 3
   gave the court reporter copies. You gave the witness
 4
 5
   copies, but you didn't give me any copies. My feelings
   were hurt. This isn't on the record.
 6
 7
             THE REPORTER:
                            It was.
 8
             MR. MORIARTY: I don't want anything taken out.
 9
             MR. ERNST: All right. Leave it in there.
             MR. MORIARTY: If you start taking things out,
10
11
   it's a slippery slope.
12
             MR. ERNST: Leave it in
13
             If you want to blow this up, you could blow it
   up to a bigger type, I will say that.
14
15
             MR. MORIARTY: Okay.
16
             Fourth column?
17
       Α
             Fourth column.
18
             Way down at the bottom. You see it says
    "Precautions"?
19
20
       Α
             Yes.
             It says, "Use in patients with impaired renal
21
   function, " colon, "Digoxin is primarily excreted by the
22
23
   kidneys, therefore patients with impaired renal function
24
   require smaller than usual maintenance doses of
25
   digoxin."
```

```
1
             Do you see that?
 2
        Α
             Yes, I do.
 3
        Q
             Do you agree with that statement?
        Α
             Yes, I do.
 4
 5
             Please go to the next page. Under "Dosage and
    Administration" it says, "Recommended doses -- dosages
 6
 7
    of digoxin may require considerable modification because
    of individual sensitivity of the patient to the drug,
 9
    the presence of associated conditions, or the use of
    concurrent medications."
10
11
             Did I read that right?
12
        Α
             Yes.
13
             Is that consistent with your experience?
14
        Α
             Yes.
15
             "In selecting a dose of digoxin, the following
16
    factors must be considered. Number 2, the patient's
    renal function preferably evaluated on the basis of
17
18
    estimated creatinine clearance."
19
             Do you see that?
20
        Α
             Yes, I do.
21
        0
             Is that consistent with your experience?
22
        Α
             Uh-huh.
23
             By the way, as patients age, can -- and if
24
    their renal function does deteriorate, can the
25
    creatinine levels still be normal?
```

1 Yes, they can be. As a matter of fact, in Number 3, in this --2 3 getting back to the label, it says, "The patient's age, infants and children require different doses of digoxin 4 5 than adults. Also advanced age may be indicative of diminished renal function even in patients with normal 6 7 serum creatinine concentrations." 8 Do you see that? 9 Yes, I do. Number 4 is "Concomitant disease states, 10 concurrent medications or other factors likely to alter 11 the pharmacokinetic or pharmacodynamic profile of 12 digoxin." 13 14 Do you see that? 15 Yes. 16 So, bottom line, are there a number of reasons why a patient might get an elevated serum digoxin level? 17 18 Α Yes. 19 Are there a lot of reasons why a patient might 20 get digoxin toxicity? Yes. 21 Α 22 And a lot of those reasons have nothing to do 2.3 with the dose ingested; is that true? 24 Α Right. 25 Is this label that we were just reading from, Q

1 the Digitek label, Exhibit 4, consistent with what you 2 read in the Lanoxin label recently, Exhibit 3? 3 Α Yes. How often do you prescribe cardiac glycoside to 4 5 your own patient population? 6 Fairly frequently. I'm not sure I can really 7 give you a percentage. 8 Do you prescribe it weekly? 9 Α Yes, sure. Have you been prescribing it for most of the 10 0 11 years of your medical practice? 12 Α Yes. 13 In your experience -- I'll get back to that 14 later. 15 For A. fib patients, at what maintenance dose 16 do you typically start them? 17 Are you talking about the digoxin? Α 18 Yes, sir. I'm sorry. 19 I'd start them at .25 milligrams. 20 Why .25 as opposed to lower doses, 125? 0 21 Α Really, it kind of depends on their age. The 2.2 125 would be a low dose for digoxin. 2.3 A lot of times, especially in the atrial 24 fibrillation, in order to control the ventricular rate 25 you have to push the dose a little bit. It needs to be

a little bit higher. 1 2 Okay. Were you in practice when the 3 .50 milligram doses of digoxin were actually still sold? I don't recall that strength. 4 5 Do patients who have hypertension have an increased risk of renal insufficiency? 6 7 Yes, they do. 8 When you prescribe digoxin products for your 9 own patients, do you have a target range that you're looking for for a serum digoxin concentration? 10 11 Α Yes. Typically between one and two. 12 Is digoxin toxicity common? 13 Α It's relatively common. 14 Does it occur in patients taking proper doses? Q 15 Α Yes. 16 Have some of your patients been taking digoxin for many years? 17 18 Α Yes. 19 In the patient population that you have that 20 has been taking digoxin for many years, are there some patients whose serum digoxin concentrations are 21 22 difficult to keep within that target range of one to 2.3 two? 24 Yes, it could be difficult to keep within that 25 target range. I might add, also, that some patients do

1 well even below the target range. 2 Sure. If they are below a serum digoxin 3 concentration of one, that does not always mean they are subtherapeutic? 4 5 Α Correct. Patients who are higher than two are not 6 7 necessarily toxic; right? 8 Correct. 9 And even patients -- have you seen patients at a digoxin level of three who were not toxic? 10 11 I don't know. I don't recall offhand. I have seen patients at a level over two, who, you know, were 12 13 not toxic. Would you agree with me that there is not --14 15 that a level of 3 or 3.5 is not necessarily fatal? 16 Correct. When do you -- if you have your choice, how 17 18 long after the patient's last digoxin dose do you draw 19 the serum digoxin concentration? 20 Six to eight hours after their dose. Why? 21 0 22 Because it takes about that amount of time, 2.3 probably about six hours, for the digoxin that's in the 24 blood to be assimilated by the tissues, so that would be 25 their steady state after about six or eight hours.

1 And that's discussed in the product label, is 2 it not? Α Yes. 3 You saw that when you read the Lanoxin label 4 5 the other day? 6 Α Yes. If you draw a serum digoxin concentration 7 before that six- to eight-hour window, it would tend to be elevated above the steady state? Yes, it would. 10 11 Do you have that -- in patients who have been 12 taking digoxin for a number of years, do you have a 13 target for how frequently you will draw their serum 14 digoxin level? 15 Yes. Yearly is usually satisfactory. 16 Do you know from reading your medical records whether you were -- whether you have yearly serum 17 18 digoxin levels on Dan McCornack? 19 In general, he was drawn once a year. 20 I was -- in looking at your chart, I was able to find serum digoxin concentrations on March 24, 1995; 21 August 1, 2001; November 14, 2002; February 20, 2004; 22 2.3 July 28th, 2006; and May 15th, 2007. 24 Do you know whether there are serum digoxin 25 concentrations that I was not able to find for the years

1 in between? 2 There may be levels from the cardiologist. 3 It's a possibility. But as far as ones that I ordered, they would be -- those would be the ones. 4 And I'm not even sure, frankly, Dr. Lemm, that 5 the dates I just read to you were all from your office. 6 Some of them may have been from Dr. Von Dollen's office. 7 I did not designate that in my notes. 9 I'm just wondering whether you're aware, from any source, as to whether there were more that I should 10 11 take into account when I analyze this. 12 No, not that I'm aware. Α 13 Q And electrolyte imbalances cause arrhythmias? Yes, they can. 14 Α 15 If a patient -- excuse me if I asked you this 0 16 before. 17 If a patient has renal insufficiency, will it 18 tend to increase the chances of them having elevated 19 serum digoxin concentrations? 20 Α Yes. 21 0 Is that because digoxin is excreted by the 22 kidneys? 23 Α Yes. 24 And if the kidneys are not working as well, the 25 drug will be essentially retained in the body more?

1 Correct. 2 Does quinine or quinidine have the potential to increase serum digoxin levels? 3 Α Yes. 4 5 Were you prescribing any medications for Mr. McCornack which contained quinine or quinidine? 6 7 Α No. Do you have any explanation for why there were 8 9 trace amounts of quinine in his blood on the postmortem specimen that was sent from the Santa Cruz coroner's 10 11 office to NMS labs? 12 Α No. 13 To your knowledge, does diltiazem have the potential to increase serum digoxin concentrations? 14 Yes, it can. 15 16 Is that information contained in the diltiazem 17 product label? 18 I expect it would be. I don't know for sure. 19 Have you read the medical literature to that 20 effect? Α Yes. 21 22 Have you ever talked to anyone at Actavis or 2.3 Mylan about the Digitek recall? 24 Α No. 25 Let's talk in a little more detail about Q

```
1
   Dan McCornack.
 2
             MR. ERNST: We've been going about an hour.
 3
   you want to take about a ten-minute break?
             MR. MORIARTY: I'm sorry?
 4
 5
             MR. ERNST: We've been going about an hour and
   15 minutes.
                 Do you want to take a break or --
 6
             MR. MORIARTY: No, but I will if you want one,
 7
 8
   or Ms. Donahue wants one, or even the court reporter.
 9
             MR. ERNST:
                        I'd like a five-minute break.
             MR. MORIARTY: You're welcome to do that.
10
11
                              (Recess.)
   BY MR. MORIARTY:
12
13
             Did Mr. McCornack have early onset atrial
   fibrillation?
14
15
             Yes, he did.
16
             He was diagnosed at about age 22, wasn't he?
17
        Α
             Yes.
18
             What does that mean? Means -- is it uncommon?
19
             Yes, it is. It's quite uncommon.
20
             So what does it mean?
        0
             Well, it means that he had an abnormal focus of
21
22
   electrical activity in his heart. You do see that
2.3
   occasionally, but it's really pretty rare.
24
             Is it likely a congenital --
25
        Α
             Yes.
```

1 -- issue? 2 Yes, it would be more likely congenital. 3 Because he was diagnosed at such a young age, he, unlike somebody diagnosed at 50, would have a 4 5 substantially longer time to be under treatment for the disease --6 7 Α Yes. 8 -- correct? 9 Do A. Fib patients run a risk of sudden cardiac death? 10 11 Α Yes, they do. 12 So he would have a much longer time to be 13 exposed to that risk? 14 Α Correct. 15 Do you know any statistics about the life 16 expectancy of patients who are diagnosed with atrial fibrillation in their early twenties? 17 18 Α No. 19 Is it likely to be reduced over the general 20 population? I'm sorry, I'm not sure I follow. 21 22 Is their life expectancy likely to be reduced 23 when compared with the general population? 24 Α I would expect so. 25 But you can't quantify it for us? Q

```
1
             No, I really can't.
        Α
 2
        Q
             Did he have hypertension?
             Yes.
 3
        Α
             Did he have arteriol sclerotic heart disease?
 4
 5
        Α
             Yes.
 6
        0
             Was he obese?
 7
        Α
             Yes.
 8
             Was he obese for many years?
 9
        Α
             Yes.
             Is obesity a risk for coronary disease?
10
        Q
11
        Α
             Certainly.
             Is it a risk for other problems?
12
        0
13
        Α
             Sure.
             Including hypertension?
14
        Q
15
        Α
             Uh-huh. Yes.
16
             And, in a sense, we have a little bit of a
    chicken and egg problem. He has obesity and he has
17
18
    heart disease and he has hypertension. It's hard to
    know what causes which; correct?
19
20
             MR. ERNST:
                         Objection.
             MR. MORIARTY: I know I'm a little bit
21
22
    colloquial today.
23
             Am I right about that?
             MR. ERNST: Objection. For the record, my
24
25
    first objection. There's some rules out there that I
```

```
can state reasons as a general rule, but we have a court
 1
 2
   order if there's an objection, whether it's compound or
   whatever, we just make one objection for the record.
 3
   doesn't mean you're not to answer the question. It just
 4
   means I've objected to the form of the question for the
 5
   Court to decide later.
 6
 7
             MR. MORIARTY: Understood.
 8
             MR. ERNST: If you understood the question, go
 9
   ahead. I assume that's acceptable to you, Mr. Moriarty?
            MR. MORIARTY: That's the rule, sir.
10
11
             THE WITNESS: Can you restate for me?
12
             MR. MORIARTY: Yes. That's what I want you to
13
   do. If I ask a bad question, if I lapse from science to
   mumbo-jumbo, I want you to tell me. I'll rephrase it.
14
15
             THE WITNESS:
                          Okay.
16
   BY MR. MORIARTY:
17
             Is it likely that Mr. McCornack, either
18
   genetically or because of his obesity, had hypertension?
19
             MR. ERNST: Objection.
20
             THE WITNESS: Yes.
   BY MR. MORIARTY:
21
22
             And then as a consequence of his obesity and
23
   hypertension, does he have increased risk of sudden
24
   cardiac death?
25
       Α
            Yes.
```

1 Does he have increased risk of coronary artery 2 disease? Α Yes. 3 So he has increased risk of heart attacks? 4 5 Α Correct. 6 Would he have increased risk of deteriorating renal function? 7 8 Yes. 9 In fact, when you reported -- or when you drew laboratory studies, did he have hypercholesterolemia? 10 Yes, he did. 11 Α From your review of his medical records, did he 12 13 state repeatedly that he had a stressful job and took no vacations? 14 15 Yes, he did. 16 Did he repeat that to you over the course of many years? 17 18 Yes, I think he did. Is stress a risk factor for heart disease? 19 20 Α Yes, it is. Is stress a risk factor for sudden cardiac 21 0 death? 22 23 Α Yes. 24 Q Why is that, by the way? 25 Α I don't know. But it's definitely a risk

51

```
1
    factor.
 2
        0
             Did he tell you that he rarely exercised?
             I don't recall.
 3
        Α
             Could you look at your note from October
 4
 5
    something 2004?
 6
        Α
             Okav.
 7
             You had a visit with him in that month.
 8
             MR. ERNST: Objection.
 9
             MR. MORIARTY: What's the objection?
             MR. ERNST:
                        Well, I don't know that exercise is
10
11
            I know he played a lot of golf, did a lot of
12
   walking.
13
             MR. MORIARTY: I'm just getting at --
14
             MR. ERNST:
                        The question are we talking about,
15
   you know, cardiovascular, yoga? What kind of exercise
16
   are you talking about?
             MR. MORIARTY: Well, you know me. I'll make
17
18
    this pretty clear on the record.
             MR. ERNST: You asked.
19
20
             MR. MORIARTY: I did.
             Look at your notes. I believe it's October 11,
21
22
    '04, if I'm correct. I might be wrong.
23
             I'm sorry. Let me withdraw that question.
24
        Α
             Okay.
25
             Okay. Did you send Mr. McCornack to a
        Q
```

1 orthopedic consult named James Carr, M.D.? 2 Yes, I did. 3 Did you ever receive any reports from James Carr, M.D.? 4 5 I need to check. Α 0 October 20th, 2004. 6 7 Yes, I have a report from Dr. Carr. 8 And in that, when he gave -- when Mr. McCornack gave Dr. Carr a social history, does it say that he exercises rarely? 10 11 Α Yes, it does. 12 All right. Now, you knew Mr. McCornack for 13 many years; correct? 14 Yes, uh-huh. Α 15 Because of his ranch and his hunting and his 16 fishing and many other things that he did, did he have a sedentary lifestyle? 17 18 I wouldn't say that he really had a sedentary 19 lifestyle. 20 All right. Do you have any characterization of his lifestyle at all? 21 22 I know he had -- I know he enjoyed playing 23 golf. 24 Okay. Q 25 I think he was a moderately-active man. Α

1 You know that he chewed tobacco? Q. 2 Α Yes. Is that any risk for heart disease? 3 Q I think it probably is, any tobacco product. 4 Α 5 It's also a risk of oral cancers, is it not? 0 6 Α Definitely. 7 At one point, did he express to you some signs and symptoms that at least caused you to refer him to an 9 ENT man? Α Yes. 10 11 0 And what was your understanding of how much 12 alcohol Mr. McCornack consumed on a daily or weekly basis? 13 I believe he drank one or two beers a day. 14 15 From your experience in the medical field, is 16 one to two beers a day a risk factor for anything? 17 It's hard to say. 18 Depends on your activity level, how much you 19 eat, things of that nature? 20 Α Right. Did you ever diagnose Mr. McCornack with 21 diltiazem toxicity? 22 2.3 Α No. 24 If Mr. McCornack had an elevated diltiazem 25 level while he was living, would that necessarily mean

1 that he took an excessive dose of diltiazem? 2 I wouldn't think so. So when you looked at the NMS Lab report of his 3 postmortem diltiazem level, you did not conclude that 4 5 the diltiazem level that was three times the normal range meant he had taken an excessive dose, did it? 6 7 Α Correct. 8 Did at, some point, Mr. McCornack ever have an elevated digoxin level would that necessarily mean that he took an excessive dose? 10 11 Α Not necessarily. 12 And when you saw the postmortem digoxin level 13 of 3.6 in the NMS Lab reports, you did not conclude from that, necessarily, that he had taken an excess dose of 14 15 digoxin, did you? 16 I would think so, at that level, yes. 17 All right. What's the basis for that 18 statement? 19 Because if his level were close to two, I would 20 think that he might still be in a therapeutic range for 21 But a patient getting over about 2.4, I'd be 22 really concerned of toxicity. 2.3 I understand what you just said, but that 24 doesn't necessarily mean he took a larger than normal 25 dose, does it?

1 However, he had been on the same dose of 2 digoxin for years, and his previous levels had been 1.6, 1.7. And so if suddenly he had a dose that -- or a 3 level that was much higher than that, I would think that 4 something has happened. He's now taking an excessive 5 dose. 6 Okay. I thought we established earlier that 7 8 even patients who took the drug chronically and stayed within your therapeutic target would, for many reasons, suddenly have an excessive level; right? 10 11 MR. ERNST: Objection. 12 THE WITNESS: It's possible, yes. 13 BY MR. MORIARTY: Okay. And even this piece of literature that 14 15 Mr. Ernst gave you concludes that postmortem levels from any source routinely exceed antemortem levels; correct? 16 17 That's what it says, yes. 18 You don't have any -- you told me before you 19 don't have expertise in toxicology; correct? 20 Α Correct ... So you don't have any formulaic way to back 21 22 calculate what his serum digoxin concentration level was 2.3 just before he died, do you? 24 Α No, I really don't. 25 Not to any reasonable degree of scientific Q

1 probability; right? 2 I'd have to leave that to the experts. 3 Did you ever render an opinion to anybody that diltiazem toxicity was a cause of Mr. McCornack's death? 4 5 No. Α Did you ever express an opinion that, because 6 7 Mr. -- I'm sorry, let me withdraw that. 8 Did Mr. McCornack take pretty much the same 9 diltiazem dose for the last few years of his life? I think he took the same dose since 2001, 10 11 if I recall correctly. 12 And you never diagnosed him with diltiazem 13 toxicity; correct? 14 Correct. Α 15 And did you see in the NMS Lab reports, that 16 Mr. Ernst showed you, that he was like three times the therapeutic range on that postmortem level? 17 18 Α I saw that. 19 But you did not conclude to a reasonable 20 probability that he had taken an excess dose of diltiazem that day or not, did you? 21 2.2 Correct. 23 Are atrial fibrillation patients generally at 24 risk of clots? 25 Α Yes, they are.

1 0 Why? 2 Because of the fact that the atrium, that 3 chamber of the heart, is not contracting correctly, it's very possible for a clot to build up inside the atrium 4 because it -- basically, the blood stagnates there, and 5 so they are at risk for clots. Do most the atrial fibrillation patients get 7 8 put on an anticoagulant? 9 Α Yes. Why was Mr. McCornack not placed on an 10 11 anticoagulant? 12 He was on an antiplatelet medication. He was 13 on aspirin. But it's true, he was not on an 14 anticoaqulant. 15 I know he had discussed that a number of times 16 with Dr. Von Dollen. I believe Dr. Von Dollen in his notes said that he was concerned about the risks of 17 18 Coumadin, the increased bleeding that Dan could have. 19 And that in discussing it with him, between the two of 20 them they decided that aspirin would be a safe therapy for him. 21 22 Was Mr. McCornack at any higher risk of 2.3 bleeding than any other A. fib patient? No, not really 24 Α 25 Q I just need to make sure I asked you this

```
1
               Did you tell me before that it's your
 2
   understanding that diltiazem can increase serum digoxin
   levels?
 3
        Α
             Yes.
 4
 5
             And in the postmortem specimen, regardless of
   whether it's reliable or not, Mr. McCornack had
 6
    increased levels of diltiazem as well as digoxin;
 7
    correct?
 9
             Correct.
             And diltiazem can cause the same sort of
10
11
    cardiac consequences that digoxin can; is that right?
12
        Α
             Yes, it could.
13
             MR. ERNST: Objection.
   BY MR. MORIARTY:
14
15
             Did you ever sign a death certificate for
16
    Dan McCornack?
17
        Α
             No.
18
             Did the coroner ever ask you to sign one?
19
        Α
             No.
20
             If the coroner had asked, would there be some
    evidence of that in your record?
21
2.2
        Α
             Yes.
23
             In -- did you ever see the original death
24
    certificate for Dan McCornack?
25
        Α
             I don't think so. I don't know. I don't
```

1 I don't recall that I did. It would have 2 been part of this record if we had a copy of it. 3 Okay. Let's go on to something else. Let's talk about the dose level that 4 Dan McCornack received of digoxin. 5 6 Starting consistently December of 1994, did he 7 receive a total dose in a day of .50 milligrams? 8 Correct. 9 And the way it was prescribed for him is what's known as BID, twice a day; correct? 10 11 Α Correct. So his dose was split 250 at two different 12 13 times per day? 14 Α Correct. 15 Did you instruct him as to when in the day he 16 should take it? Typically morning and evening. 17 18 All right. Who made that initial dosing decision? 19 20 The cardiologist. Do you know who the cardiologist was at that 21 time back in '94? 2.2 2.3 I believe it was Dr. Von Dollen. 24 Could you check your notes, because I think 25 there was another name in there, and it might have been

1 a partner of Von Dollen's, or it could have been 2 somebody who is now retired. I just want to know --Α Sure. 3 -- because you'll know the doctors around here 4 5 better than I do. The first record that I have regarding from 6 Dr. Von Dollen is from '92, and it was a note sent to 7 Dr. Morgan, who is an internist, who also did a lot of cardiac --Q 10 Okay. 11 -- evaluation. So the cardiologist made that 50 milligrams a 12 13 day dosing decision; correct? 14 Α Correct. 15 Then you carried it over? 16 Α Correct. 17 If you felt the need, did you have the power to 18 change his dose if you wanted? 19 Α Yes. 20 Did you ever make any recommendations to change his dose? 21 2.2 Α No. Did anybody ever try him on lower doses? 23 24 Α Yes. I have a note from Dr. Von Dollen from 25 '98, and at that time he was on .25 milligrams once a

61

Gordon Lemm, MD

1 day. And how did Mr. McCornack do on that dose? 2 I believe he still had some -- well, I don't 3 Α know how he did on that dose. My next note regarding 4 5 that is from the next year. Give me the date of the visit, please. 6 7 Α 9-1-99.8 Okay. 9 And at that time, he was taking the Lanoxin twice a day. 10 11 Q All right. So, do you know whether he was 12 actually given a good solid try on a lower dose? 13 Α I don't know. 14 All right. If a patient hypothetically was 15 consistently taking digoxin with double the active pharmaceutical ingredient, would you expect them, at 16 some point, to show some signs or symptoms of digoxin 17 18 toxicity? 19 MR. ERNST: Objection. 20 THE WITNESS: Usually, they would. BY MR. MORIARTY: 21 22 If a patient who was on a total dose of .5 per 23 day spread out over the two doses of .25, was 24 consistently taking tablets with double the active 25 pharmaceutical ingredient, would you expect them to show

1 some signs of digoxin toxicity? 2 They probably would. Let's assume for today that Mr. McCornack's 3 atrial fibrillation required the dose level that he was 4 5 receiving to adequately control his A. Fib. Okay? Α 6 Okay. Is that reflective of the severity of his 7 8 disease that it takes that much to control it? 9 I'm not sure that would be the case. Why? 10 0 11 Α Well, perhaps so. In that if -- if it required a higher dose to control it, I think what you might say 12 13 is that his atrial fibrillation was more frequent. quess that would be another way of saying it was more 14 15 severe. So, you know, if the atrial fibrillation is not 16 controlled at the lower dose, then it would be 17 18 reasonable to move up to a higher dose to keep his 19 ventricle from going too fast. 20 Okay. Do you remember times when he actually was administered more than .5 per day? 21 2.2 Α No. 2.3 I'd like you -- were you in pretty consistent 24 communication with Dr. Von Dollen about Dr. Von Dollen's 25 consults with Mr. McCornack?

1 I'd say so. 2 Do you have any notes from when Dan McCornack saw Dr. Von Dollen on February 16th of 2000? 3 I'll check. 4 Α 5 That was February 16th, 2000. Α Yes, I do have a note. 6 7 Look at that note, because it appears to me 8 that for some period of time they were actually giving him 1 milligram per day. MR. ERNST: Objection. 10 11 THE WITNESS: I'm sorry, I don't see that. Maybe you can point it out to me. 12 13 MR. MORIARTY: Schlep these things across the I better use them at least once. 14 country. 15 Did I say February 16th, 2000? 16 February 16th, 2000, right. 17 Okay. Look on that note, February 16th, 2000. 18 You have a typed note from Dr. Von Dollen's office? 19 Α Yes, I do. 20 I want you to look under the "Current Medication" section. Do you see that? 21 2.2 Α Yes. 23 0 Right under that is "Chief Complaint"? 24 Α Yes. 25 The last -- there's a sentence there that says Q

```
1
   he doubled up on his Lanoxin? Do you see that?
 2
             I see that now.
 3
        Q.
             All right. What that means to me is that he's
    then taking .50 twice a day, or in whatever dose, to
 4
 5
   reach 1 milligram per day.
 6
             MR. ERNST:
                        Objection.
 7
             MR. MORIARTY:
                            That's fine.
 8
             MR. ERNST:
                        Speculation on a document.
 9
             MR. MORIARTY:
                            I understand that, Don.
             Do you know anything about this incident?
10
        0
             No, I don't.
11
        Α
12
             Let's assume that, and I'll ask about --
13
   Dr. Von Dollen all about this on Monday, but let's
   assume that Mr. McCornack was taking double what he was
14
15
    supposed to be for some reason in this period of time.
             Is there anything in Dr. Von Dollen's note of
16
    February 16th, 2000, to indicate that Dr. Von Dollen was
17
18
   suspicious of digoxin toxicity?
19
             No, I don't see anything that makes -- that
20
   looks like he was suspicious.
             And a patient could accidentally or
21
22
    intentionally take too much digoxin for a short period
2.3
   of time without causing fatal arrhythmias; is that true?
24
       Α
             Yes.
25
             Was -- you know what drug tolerance is, do you
```

```
1
   not?
 2
        Α
             Yes.
             Is digoxin a kind of drug which you develop a
 3
    tolerance?
 4
 5
             I wouldn't think so.
             Well, was Mr. McCornack tolerant at least of
 6
 7
    .50 per day?
 8
                   I mean, he was tolerant in that he had no
 9
   side effects.
                   So -- and please check me, but I've got
10
11
    some notes here.
             I see that Mr. McCornack had elevated uric acid
12
13
    levels on 11 occasions spread between August of 1994 and
   May of 2007?
14
15
        Α
             Correct.
16
             Any reason to question me on that?
17
             MR. ERNST:
                        August '94 through what?
18
             MR. MORIARTY: May of '07.
19
             What was your opinion to a probability as to
20
    the cause of his elevated uric acid cause?
21
        Α
             He had gout.
22
             What is gout?
             Gout is increased uric acid level. Sometimes
2.3
24
    it's -- oftentimes it's inherited, and typically it's
25
   manifested by arthritis where there's a very sudden
```

1 painful red swelling of a joint. 2 Did he have arthritis from time to time? 3 Α Yes, he did. Can elevated uric acid levels also occur with 4 5 leukemia? 6 Α Yes, they can. 7 Can they also occur with renal insufficiency? 8 Uh-huh, yes. 9 0 He was on a medication called Allopurinol? 10 Α Correct. 11 0 Is that for gout? 12 Α It's for gout. 13 Mr. McCornack, according to your records, had ten instances of elevated SGPT levels between 14 15 August 1994 and April 2005? 16 MR. ERNST: Now what is that? Repeat that. 17 MR. MORIARTY: SGPT. 18 MR. ERNST: Objection. BY MR. MORIARTY: 19 20 Are you aware of that? 0 21 Α I'm looking at my records. 22 Yes, I recall that there were some elevations. 2.3 Did you ever develop an opinion to a reasonable 24 degree of medical probability as to the cause of his 25 SGPT elevations?

1 Very likely, there are two potential common 2 One is alcohol intake, and the other is a 3 condition called fatty liver, where there's fat infiltration into the liver. Both of those will cause 4 that to happen. 5 What are the risks of fatty liver? 6 7 Vast majority of time, there really is no risk 8 to fatty liver. 9 0 Okay. In extremely rare instances, it will lead to 10 11 cirrhosis, but that's very rare. 12 According to your records, between June of 2001 0 13 and May of 2007, Mr. McCornack had nine instances when his BUN was elevated. 14 15 Are you aware of that? Yes, I see those in the record. 16 Is that most likely because he had some degree 17 18 of renal insufficiency? 19 That's really hard to say. And the reason why I say that is because many times when we have patients 20 21 draw fasting samples, they are a little bit dehydrated. And a little bit of dehydration will also increase that 22 2.3 BUN. So it's a common occurrence on lab work. If the patient on a fasting draw has a little 24 25 bit of dehydration, what else would be abnormal in those

1 draws? 2 Um, it's usually just the BUN. Did he ever have an elevated creatine? Look at 3 August of 2002. 4 5 Yes, he had a slightly elevated creatine of 1.6 at that time. 6 Did he have an elevated BUN the same day? 7 8 No, he did not 9 Did you ascribe any reason to the cause for his elevated creatine level at that point? 10 11 Α Nothing in particular at that point. 12 Have you developed any opinion to a reasonable 13 probability as to whether Mr. McCornack had any renal 14 insufficiency at all? 15 I don't really have any opinion on that. I 16 doubt that he did. He had an HLAV 27 positive antigen back in 17 18 2004. What was that? 19 HLAV 27 is a genetic marker for certain forms 20 of arthritis. And the classic is a condition called 21 ankylosis spondylitis. 22 Is that what the conclusion was ultimately in 2.3 his case, that that's what his elevated HLAV 27 was? 24 Α I think so. 25 And the last serum digoxin concentration I find

```
1
    in your records is -- or in any record -- let's put it
 2
    that way, is May 15th, 2007. Is that in your record?
             Yes, it is.
 3
        Α
             And it was 1.6?
 4
 5
        Α
             Correct.
 6
        0
             No others close in time to his death?
 7
             Not that I'm aware of.
             And there were no electrocardiograms in the
 8
   last couple months of his death?
             Not that I'm aware.
10
11
        0
             Have you ever done any research about
12
   postmortem redistribution of digoxin, besides reading
   Exhibit 2?
13
14
        Α
             No.
15
             Do you consider yourself to be an expert on
16
   postmortem redistribution in general?
17
        Α
             No.
18
             And therefore not on either diltiazem or
19
    digoxin; correct?
             Correct
20
        Α
             Are you going to express any opinions in this
21
22
    case either way about the reliability of the postmortem
2.3
    digoxin level of 3.6?
24
             MR. ERNST: Objection.
25
             THE WITNESS: Can't really give an opinion
```

1 about the reliability of it. 2 BY MR. MORIARTY: Q Okay. Do you have some opinion? I mean, I 3 could use a lot of different words here. 4 5 Α Sure. Accuracy, reliability, meaning are you going to 6 7 render any opinions about the meaning of that 3.6? 8 Well, I would be really concerned that this was 9 a toxic level. 10 Q Okay. 11 That's -- looking at that 3.6 level. 12 Okay. And that's fine, but I'm asking you as a 0 13 physician and a scientist. You've already told me you're not a toxicologist. 14 15 Correct. 16 You don't have any training in pharmacokinetics or pharmacodynamics; correct? 17 18 Α Right. 19 You've never even studied postmortem 20 redistribution of digoxin; correct? Α 21 Correct. 22 Have you ever even seen a postmortem digoxin level before that one? 2.3 24 Α No. 25 So, do you have the training, knowledge and

```
1
   experience to draw conclusions, to a reasonable degree
 2
   of medical probability, about what that 3.6 postmortem
   level means in Mr. McCornack's case?
 3
             MR. ERNST: Objection.
 4
 5
             THE WITNESS: I'm not an expert in that. I
   still would be worried, though, with a 3.6. Definitely
 6
 7
   throw up a red flag.
   BY MR. MORIARTY:
 9
             Sure. We'd all be worried and throw up red
10
   flags. But that does not mean you have an opinion to a
11
   reasonable degree of medical probability about it;
12
   correct?
             MR. ERNST: Objection.
13
             THE WITNESS: I'm not really sure what that
14
15
   means as far as "reasonable probability." But it would
16
   concern me. It would concern me.
   BY MR. MORIARTY:
17
18
             I didn't see the NMS Lab report in your
   records, but no matter, I have a copy of it here.
19
20
             The diltiazem section, are you concerned that
   he had a toxic level of diltiazem?
21
22
             Um, I honestly, I'm not really sure what that
2.3
            I'm not used to seeing diltiazem levels.
   means.
24
             Well, you have a level of digoxin that is
25
   outside the range that would be your target; right?
```

1 Correct. 2 And you have a diltiazem level that is three 3 times what this lab says is normal range; correct? 4 Α Yes. 5 So, if you're concerned about digoxin possibly being a toxic level, you would, by sure force of logic, 6 7 have to be concerned that the diltiazem level was toxic wouldn't you? 9 MR. ERNST: Objection. THE WITNESS: I would want to investigate it 10 11 and see if that kind of level could cause problems. BY MR. MORIARTY: 12 13 Just as you would want to investigate further about what postmortem levels of digoxin really mean? 14 15 Α Right. 16 To your knowledge, did Dr. Winkle or Dr. Von Dollen ever suggest to Dan McCornack that he get 17 18 radiofrequency ablation? 19 Α Yes. 20 Was that in the summer of 2007? 0 I believe so. 21 Α Yes. 22 0 Did he ever get that procedure done? 23 Α No. 24 Q Do you know why? 25 I think he just basically decided against it. Α

1 And I -- I'm not sure why. There is a note that I have from Dr. Von Dollen 2 from November of '07. It said Dan wanted to hold off on 3 ablation due to the hunting season. He's unclear how to 4 proceed. He was feeling relatively well, and so I think 5 he was undecided about that. Do you know much about -- I'm sorry, I didn't 7 8 mean to cut you off. 9 I know that -- I remember on an occasion or two that also I had approached the subject with Dan, and he 10 11 was uncertain about what he wanted to do there. 12 Do you know anything about radiofrequency 13 ablation? I've had several patients who have had it done, 14 but I'm not very familiar with the procedure itself. 15 Is it a procedure designed to save or prolong 16 cardiac function? 17 18 Α Yes. So, that procedure is potentially lifesaving? 19 20 Α Yes. Does it substantially reduce the risk of sudden 21 22 cardiac death from any cause? 2.3 Yes. I expect it would. 24 If a patient has radiofrequency ablation, is it 25 typical that they are then able to take lesser doses of

1 calcium channel blockers and cardiac glycosides? 2 Yes. 3 And in the process reducing the risk of drug-to-drug interactions --4 5 Α Correct. 6 -- and their complications? 7 Α Correct. At autopsy, Mr. McCornack had a nasal strip on 8 9 his nose. You know what those are? Α Yes. 10 11 I'll just assume for today that he went to bed 12 with it on. Did you ever talk to him about using those? 13 Α I don't recall that I did. 14 Did you ever suspect that Mr. McCornack might 15 have obstructive sleep apnea? 16 Not that I recall. 17 Do you know anything about how often he used 18 those? 19 Α No. 20 Are they prescription or over-the-counter? 0 They are over-the-counter. 21 Α Look at your records from May of 2008, please. 22 Q 23 It appears --24 Α Oh, yes. 25 Did you have some discussions with Q

```
1
   Kathy McCornack in around that period of time?
 2
             Yes, on May 13th.
 3
        Q
             Tell me everything you remember --
       Α
 4
             Okay.
 5
             -- about that conversation.
 6
             Um, my note states she's concerned he may have
   been on recall digoxin and it may have contributed to
 7
   his M.I. However, his digoxin level was zero. Puzzling
   because he always took his medications.
             We reviewed his med list and signs of digoxin
10
11
   toxicity.
12
             I remember asking her if he had had a dig level
13
   done, and she said, "I am not really sure, but I think
   maybe there wasn't any digoxin in his system."
14
15
             I think she was guessing at that point. But
    that issue was raised by her in that phone call.
16
             At the end it says, "We reviewed his med list
17
18
   and signs of dig toxicity."
19
             Do you see that?
20
        Α
             Yes.
             I assume you had some discussion with her about
21
22
   all of the medications he was taking; is that fair?
2.3
        Α
             Yes.
24
             And signs and symptoms of toxicity from any of
25
   them; correct?
```

1 Uh-huh, yes. Α 2 0 Including digoxin? 3 Α Correct. And I take it that, at that point, she did not 4 0 5 describe to you something about his course that day or night that made you suspect digoxin toxicity? 6 7 Α Correct. 8 And if a -- when a patient comes to your 9 office, your medical assistant and you, do you ask for a medical history? 10 11 Α Yes. 12 And in a patient with digoxin, that medical 13 history would be some of the kind of clinical evidence that you would use in assessing whether they had digoxin 14 15 toxicity or not? 16 Definitely. And I think we may have covered this before, 17 18 but I've got to be careful because I don't get to California that often. 19 20 You're looking at the clinical, and then the 21 electrocardiograms, and then, I assume, digoxin levels? 2.2 Correct. Α 2.3 Since we have no predeath electrocardiograms 24 and serum digoxin concentrations, this discussion with 25 Kathy McCornack was the only information you had from

```
1
   the clinical side; right?
 2
       Α
             Correct.
 3
             Is there anything else about that discussion
   that you recall?
 4
 5
       Α
             No.
             Have you ever had any other discussions with
 6
 7
   Kathy McCornack about the cause of Dan's death after
    that discussion?
 9
             No, not really.
             It's not something she typically talks with you
10
11
   about when she comes to see you for her own medical
   problems?
12
13
             No. I ask her how she's doing, and she relates
   how she's doing. But we've not really discussed further
14
   about this.
15
16
             MR. MORIARTY: Go off the record.
                  (Discussion held off the record.)
17
18
             MR. MORIARTY: Back on the record.
19
             I asked you some questions about postmortem
20
   redistribution. Let me just ask one more about that.
             Do you have any knowledge about how long after
21
   death a postmortem blood specimen needs to be drawn in
22
2.3
   order for it to be considered reliable so far as digoxin
24
   is concerned?
25
             I have no information on that.
```

1 All right. You did receive Dr. Von Dollen's 2 July and November of 2007 notes, did you not? Yes, I have a note from him dated 11-29-07, and 3 the one prior to that. 4 5 Should be July of '07? Q. Correct. July of '07. 6 7 When Mr. McCornack came to your office, would you typically have reviewed Dr. Von Dollen's notes and 9 then discussed them with Dan McCornack? Α Yes. 10 11 So, as far as the status and the plan, or the 12 recommendations, you'd go over that with him? 13 Α Right. I think I found about six notes readily 14 15 available to me in your chart between August of 2000 --16 I'm sorry, June of 2001 and November of 2007 in which Dan McCornack complained of persistent fatigue? 17 18 Α Yes. 19 Is that a complaint he made to you frequently? 20 Α Yes, he did. 21 Do you have an opinion as to the likely cause 22 of his persistent fatigue? 2.3 Um, yeah, my opinion is that it was stress 24 related. 25 Can patients who have atrial fibrillation have

1 persistent fatique? 2 Oh, absolutely. Yes. That would be another 3 I guess I would say there are three potential reasons for him. One was stress, which we talked about, 4 5 and another would be his conditioning, his physical conditioning. And then the other, certainly the atrial 6 7 fibrillation. Did you ever diagnose him with depression or 8 9 treat him for depression? Look in April of '07. I did diagnose him with stress reaction. 10 11 Was he treated with any sort of prescription medications for stress or --12 13 Α I don't recall --14 -- depression? Q 15 -- that I ever had him on medication for that. Α 16 Did you instruct him to lose weight? Q 17 Yes. Α 18 Repeatedly? 19 Α Yes. 20 And he essentially did not; correct? 0 Correct. 21 Α To the best of your knowledge, was he compliant 22 2.3 with his medication prescriptions? 24 Α Yes. 25 Did his atrial fibrillation get worse over Q

```
1
    time?
 2
             I don't think it really did. I don't recall
    that it did.
 3
        0
             Okay.
 4
 5
             I think early on, from some of the notes I've
    seen from Dr. Von Dollen, initially it was difficult to
 6
 7
             But I think from, you know, for the four or --
   four years that I saw him, I think it was pretty much a
   steady state.
             All right. Let me ask you to assume that
10
11
    originally Mr. McCornack was on no digoxin for his
12
   atrial fibrillation, then .25 per day, then .5 per day.
13
             That by May of 2001, there were plans for him
    to wear a halter monitor.
14
             That in July of 2001, they increased his
15
16
    diltiazem. And that by 2007 the cardiologists were
    recommending radiofrequency ablation.
17
18
             Assuming all those to be true, is that sort of
    scenario an indication that his atrial fibrillation was
19
20
   more difficult to control?
             MR. ERNST: Objection.
21
22
             THE WITNESS: It could be, yes.
2.3
   BY MR. MORIARTY:
             Well, is it likely?
24
        Q
25
        Α
             Yes, I'd say it's likely.
```

1 In those years, is it your opinion that he was 2 given adequate medical therapy for his atrial fibrillation? 3 Α Yes. 4 5 Did he frequently complain of chest pain? Α I don't think it was a frequent complaint, but 6 it did happen occasionally. 7 And when it did, you and Dr. Von Dollen 8 9 investigated whether that was cardiac in origin? Correct. 10 11 Did he ever explain -- I'm sorry, did 12 Mr. McCornack -- let me repeat. 13 Did Mr. McCornack ever complain about visual loss associated with a drug called Atropine? 14 15 I believe I recall seeing a note from 16 Dr. Von Dollen that said he did not tolerate the medication, but I don't recall why. 17 18 Okay. Had you ever met Mr. Ernst before he 19 talked to you about Mr. McCornack's death? 20 Α No. Never worked with him on any other lawsuits? 21 0 2.2 Α Not that I recall. 2.3 Did Mr. Ernst tell you anything about what the 24 NMS Laboratory's forensic toxicologist testified to this 25 past Tuesday about the postmortem digoxin level of 3.6?

1 Um, I think he mentioned to me this morning 2 that that question was brought up with him, and he said it was a peripheral blood, and I think that was 3 basically the conversation. 4 5 Did Mr. Ernst tell you whether the NMS forensic toxicologist said anything about the reliability of 6 7 postmortem serum digoxin concentrations in predicting antemortem levels? 9 I don't think there was any specific talk about that. 10 11 Have you ever had any dealings with Dr. Mason, the Santa Cruz County coroner before? 12 13 Α No. 14 Now, Mr. Ernst showed you this amended autopsy and death certificate --15 16 Yes. Α 17 -- this morning; right? 18 Α Correct. Is it your understanding that the Santa Cruz 19 20 County coroner, after one and a quarter years, changed the autopsy and death certificate just two days ago? 21 2.2 Α Yes. 2.3 Did Mr. Ernst tell you that Dr. Mason changed 24 those reports after Mr. Ernst had hired Dr. Mason as an 25 expert in this case?

```
1
        Α
             No.
 2
             Have you ever heard of a coroner changing an
 3
   autopsy cause of death in a death certificate after one
   and a quarter years?
 4
 5
             Not that I recall.
       Α
             Have you ever heard of a coroner changing an
 6
 7
   autopsy or a death certificate cause of death after
   being hired by a plaintiff as a consultant in civil
 9
   litigation?
        Α
             No.
10
11
        0
             Does that strike you as a little unusual?
12
             MR. ERNST: Objection.
13
             THE WITNESS: Could be, yeah. I would think
14
   so.
   BY MR. MORIARTY:
15
16
             Have you ever seen anything in any material to
    indicate to you that, to a probability, Mr. McCornack
17
18
    took Digitek with excessive doses of the active
19
   pharmaceutical ingredient in it?
20
             MR. ERNST: Objection.
             THE WITNESS:
21
                          No.
22
             MR. MORIARTY: Okay. What I would like to do
2.3
   is take five minutes, get a glass of water, look through
24
   my notes, talk to my excellent colleague here, and then
25
   wrap up my initial role in this. Okay?
```

```
1
             THE WITNESS:
                           Okay.
 2
                              (Recess .)
             MR. MORIARTY: We're almost done here, sir.
 3
        0
             I'd like you to look at your chart, August 17,
 4
 5
   1994.
 6
        Α
             Yes.
 7
             In there there's a name of a Dr. Harvey?
 8
        Α
             Yes.
 9
        0
             Who is he or she?
             Dr. Harvey was the first cardiologist in this
10
11
   area.
             Does he still practice in this area?
12
13
        Α
             No.
                  He's been retired -- I think he retired
   before I came here in '89.
14
15
             And towards the bottom of that, there's
16
    something in your chart about getting old records?
17
        Α
             Correct.
18
             Did you ever get any old records?
19
             The only old records that I got were from
20
    Dr. Von Dollen, and it's that letter -- it's a letter
    dated December 23, '92, to Dr. Morgan.
21
22
        Q
             Okay.
23
             And let me see if there's anything else.
24
             And there was a halter monitor summary attached
25
   to that.
```

1 All right. May I have your chart for a second? 2 Α Yes, sir. Without sitting here comparing this chart page 3 Q by page, I am pretty confident that our records service 4 5 got what I'm going to describe as the right half of your chart --6 7 Α Okay. 8 -- but I don't think we got the left half --9 Α Oh, okay. -- which is more administrative kind of things. 10 0 11 Α Yes. 12 Can you have your staff make a copy of the left 13 half of this chart? 14 Α Yes. 15 If the court reporter wants to stay and take 16 the copy with her, that's fine. If you just want to ship it to me, that's fine. 17 18 Mr. Ernst will either maybe get a copy from me 19 or from the court reporter. And make sure, if you 20 would, that they get both sides of these pages. Is that okay? 21 22 Α Okay. 23 Now -- but in here, there is one thing I want 24 to ask about. 25 Now, this document, I just -- I stuck it in Α

```
1
    here this morning.
             That's fine. I'd like a copy of that, too.
 2
 3
        Α
             Okay.
        0
             Let me find what I want
 4
 5
             Okay. I'm sorry, this is going to be easier if
    I step over here. Do you mind?
 6
 7
             That's fine.
        Α
 8
             At the top, and this is on the left side of
    your chart as we look at it, it says "Prescription
    Clarification Request." Do you see that?
10
11
        Α
             Yes.
12
             Is Caremark a physical pharmacy or is it a mail
13
    order?
14
             It's a mail-order pharmacy.
        Α
15
             And it says this has to do with Lanoxin?
        0
16
        Α
             Correct.
17
             .25 milligrams; right?
        0
18
        Α
             Uh-huh.
             That's a "Yes"?
19
20
        Α
             Yes.
             And the form says, "Please clarify," colon,
21
22
    "this prescription exceeds the maximum recommended daily
    dosage of 1.00 tab"?
23
24
        Α
             Yes.
25
             And I assume what they are referring to is not
        Q
```

1 a dose, but a number of tablets; right? 2 Α Yes. Do you have any -- first of all, did you call 3 them and talk to them about this? 4 5 Α No. 6 Did you have one of your staff call and talk to 7 them? 8 We would have faxed back the reply. It was --9 they faxed this form to us. Got it. 10 0 11 Α I wrote this. 12 And read what you wrote 13 Α It says, "Patient has atrial dysrhythmia and takes two tablets daily. He has a therapeutic level." 14 15 0 Okay. 16 And this would have been faxed to them on that 17 date. 18 All righty. 1 - 28 - 05. 19 Α 20 Is it fair to assume that Caremark just has some red flag system in its computer that picks up this 21 kind of stuff? 22 23 Α Yes. 24 All right. Do you have any other materials 25 regarding this case that are not in this chart and that

```
we have not already discussed today?
 1
 2
       Α
             No.
 3
             Do you have any other opinions regarding the
   cause of Mr. McCornack's death, that we have not
 4
 5
   discussed today?
       Α
             No.
 6
 7
             MR. MORIARTY: Then I have no more questions.
 8
             MS. DONAHUE: I have no questions.
 9
             MR. MORIARTY: Mr. Ernst has the right to ask
10
   you questions.
11
             MR. ERNST:
                        I do have a series of questions.
12
             MR. MORIARTY: Are you going to be long?
13
             MR. ERNST: Yes.
                               Why?
14
             MR. MORIARTY:
                            I just wanted to know.
15
             MR. ERNST:
                        Actually he's asking for a
16
   multitude of reasons. I would like to think it's
   because he's concerned about my welfare. I think he's
17
18
   concerned about visiting his wife.
19
             I don't think I'll be long. We'll move on.
20
             MR. MORIARTY: I actually only asked because
21
   you asked me.
22
             Does this amaze you that and we have this
23
   byplay going here?
24
             Off the record.
25
             MR. ERNST: I want it all on the record.
```

```
1
             MR. MORIARTY: Let's go, because I do want to
 2
    see my wife.
             THE WITNESS: It doesn't. The first time I
 3
    gave a deposition I saw this, and I realized that, you
 4
 5
    know, it's just common.
 6
             MR. MORIARTY: We're very civil.
 7
             THE WITNESS: You gentlemen are professionals.
 8
             MR. MORIARTY: We're very sick people.
 9
10
                           EXAMINATION
11
   BY MR. ERNST:
12
13
             Doctor, would you consider yourself the
    treating physician for Daniel McCornack?
14
15
             Yes.
16
             And you are the person that has seen
    Danny McCornack for a long number of years, over 15
17
18
   years?
19
             Um, I saw him since --
20
             MR. MORIARTY: '94 to 2008.
   BY MR. ERNST:
21
             94.
2.2
                  Fourteen years?
23
             Fourteen years.
24
             And you were asked a whole host of questions
25
   about possibilities, but I want to now ask you
```

1 Doctor, do you have an opinion as to whether 2 or not Daniel McCornack had renal insufficiency? My opinion is that he did not. 3 And, Doctor, is it your opinion that 4 5 Danny McCornack was taking an adequate medication level of digoxin with the testing results being approximately 6 1.6 when you tested him annually? 7 8 Yes. 9 And you were comfortable that his digoxin levels were properly therapeutic? 10 11 Α Yes. 12 And, Doctor, based upon your training, 13 experience, seeing Dan McCornack on a regular basis, do 14 you have an opinion as to whether or not he was 15 compliant in taking his medication, that is he took it 16 regularly and as directed? 17 Yes, I think he did. 18 And, Doctor, based upon your training and 19 experience, your clinical observations of 20 Danny McCornack, and a review of the toxicology that his digoxin level of 3.6, and I believe it's been marked as 21 an exhibit? 2.2 2.3 MR. MORIARTY: It hasn't. MR. ERNST: It's not. 24 25 MR. MORIARTY: But we all know what it is.

```
1
    let's proceed.
 2
             MR. ERNST: We'll mark this next in order.
                  (Plaintiffs' exhibit 5 was marked
 3
                  for identification ()
 4
   BY MR. ERNST:
 5
             You have reviewed this, what's been marked as
 6
 7
   Exhibit 5?
 8
        Α
 9
             And you are aware of your clinical observations
   with Mr. McCornack?
10
11
        Α
             Yes.
12
             And as you sit here today, do you have an
13
    opinion that Mr. McCornack died as a result of digoxin
14
    toxicity?
15
             MR. MORIARTY: Objection.
16
             THE WITNESS: That would be my opinion.
17
   BY MR. ERNST:
18
             And you base that opinion on what?
             I based it on the fact that he died from a
19
20
   ventricular arrhythmia, and I don't have other good
   reasons for it, and the digoxin level was high.
21
22
             And you're aware that you've been questioned
2.3
   about postmortem redistribution and so forth, and you
24
    can always do more research on a whole host of things;
25
   true?
```

1 True. 2 But as the treating physician, the person that 3 saw him on a regular basis, as you sit here today, is it your opinion that digoxin toxicity led to 4 5 Mr. McCornack's death? Α Yes. 6 7 Now, I want to talk for a moment about how 8 digoxin toxicity could lead to his death. 9 As you're aware, he expired early in the morning, after midnight. 10 11 Is digoxin toxicity, based on your training and experience and clinical knowledge, could it lead to a 12 13 slowing of the heart rate? 14 Α Yes. 15 MR. MORIARTY: Objection. Form. 16 BY MR. ERNST: 17 Please state for me how digoxin toxicity, what 18 effect digoxin toxicity would have on a heart. 19 What normally would happen with digoxin 20 toxicity is that it would slow the electrical pathways of the heart. 2.1 22 Digoxin is known to cause pretty much every 2.3 kind of rhythm problem in the heart, the most dangerous 24 being ventricular fibrillation. And ventricular 25 fibrillation is a fatal rhythm unless it's corrected

1 within a few minutes. 2 Now, sometimes you can -- with digoxin toxicity 3 you can have nausea or dizziness? 4 Α Correct ... 5 And sometimes there's none of that? 6 Α That's correct. 7 And sometimes if one is asleep and suffering 8 from digoxin toxicity, their heart could just slow to a 9 level where this would become -- they would pass out and eventually die? 10 11 Α Yes. 12 You believe that's what happened here --13 Α I think so. -- Doctor? 14 Q 15 MR. MORIARTY: Objection. Form, by the way. 16 Move to strike. BY MR. ERNST: 17 18 Doctor, the opinions that you have just stated 19 were stated before you became aware that the physician 20 who performed the autopsy, Dr. Mason, had changed his death certificate; isn't that true? 21 2.2 Yes, that's true. 23 MS. DONAHUE: Objection. 24 BY MR. ERNST: 25 In other words, the opinions that you have Q

```
1
   expressed here, you have expressed previously to me
 2
   telephonically?
       Α
 3
             Correct.
             They occurred before Dr. Mason ever -- you
 4
 5
   became aware that he changed his death certificate?
 6
       Α
             That's correct.
 7
             Before you are aware that he was even
 8
   considering doing that?
 9
             That's correct.
             MR. ERNST: That's all I have.
10
11
             MR. MORIARTY: I may want to organize my notes
12
   here.
13
             MS. DONAHUE: For the record, I join
   Mr. Moriarty's objections on behalf of my client.
14
             MR. ERNST: I have a few more questions.
15
16
   BY MR. ERNST:
             Mr. Moriarty has given you a whole host of
17
18
   possibilities and things that could happen and that
19
   might be done. But what you have said here today, is
20
    that what you believe in your heart, based upon your
   knowledge, training, your clinical experience with this
21
22
   patient, and the knowledge that you have to date?
2.3
        Α
             Yes.
24
             MS. DONAHUE: Objection
25
             MR. ERNST: Thank you.
```

```
1
                      FURTHER EXAMINATION
 2
   BY MR. MORIARTY:
 3
             This opinion you've given to a probability, and
 4
 5
   that when Mr. Ernst asked you, you are talking about a
    toxicological or pharmacological reaction between a drug
 6
 7
   and a death; correct?
 8
             MR. ERNST: Objection.
 9
             THE WITNESS: Correct.
   BY MR. MORIARTY:
10
11
             And what I need to know is how as a scientist
12
   and a physician, when you're not a toxicologist or a
13
   pharmacologist, and you've never experienced before
   diagnosing digoxin toxicity as a cause of death,
14
15
   especially based on a postmortem level, you are
16
   qualified to render an opinion to a reasonable degree of
17
   medical probability on that topic.
18
             It's just my opinion. I admit I'm not an
19
   expert in it. That's just my opinion.
20
             Okay. And is it your opinion that, despite the
   one and only piece of literature that Mr. Ernst gave you
21
   about the reliability of postmortem digoxin levels, that
22
   somehow that 3.6 is a reliable indicator of what his
2.3
24
   level was before he died?
25
             I don't know that that was -- is what his level
```

1 was before he died. 2 Okay. And do you know that that level was drawn over 70 hours after his death? 3 No, I didn't know. 4 5 You would want to know as a scientist and a physician in rendering accurate testimony about cause of 6 death, what the forensic scientists, toxicologists from 7 NMS Laboratories said about Exhibit 5? 9 Sure. And I want you to assume that the five 10 Okay. 11 or six tablets that Mr. Ernst had tested for NMS were within the specifications, at least according to NMS. 12 13 Okay? MR. ERNST: Objection. 14 BY MR. MORIARTY: 15 16 I want you to assume. Okay. May I ask you, within specifications, 17 18 you're stating that the five or six tablets, had the 19 proper dose of digoxin? 20 According to the test run by NMS. 21 Α Okay. 22 You're not going to speculate about the digoxin 2.3 level in untested tablets in his prescription, are you? 24 Α No. 25 Okay. And Mr. Ernst went through all this with Q

```
1
   the possible brachycardia that can come from digoxin in
 2
    the diltiazem product label, and we can get this from
 3
   the PDR if we need to, among the cardiovascular risks
   are arrhythmia, A.V. block, bundle branch block,
 4
 5
   tachycardia, and some other issues, all of which can
   cause sudden cardiac death; right?
 6
 7
        Α
             Right.
             MR. ERNST: Objection.
 8
 9
   BY MR. MORIARTY:
             And when Mr. Ernst asked you that opinion about
10
        0
11
    the digoxin, he didn't ask anything about what role
12
   three times the normal level of diltiazem may have
13
   played in causing arrhythmias, did he?
14
             MR. ERNST:
                        Objection.
15
             THE WITNESS: Correct.
16
             MR. MORIARTY: I don't have anything else.
17
             Do you have anything else, Don?
18
             MR. ERNST: No.
19
             Has anything he said, or questions, changed
20
   your opinions at all, Doctor?
             THE WITNESS: No.
21
22
             MR. ERNST:
                        Thank you. I have nothing else.
2.3
             MR. MORIARTY: All right. What do you want to
24
   do about reading and signing?
25
             MR. ERNST: Well --
```

```
1
             MR. MORIARTY: I prefer that he do it. So,
 2
   you're going to get a transcript, from either a court
 3
    reporter or from Mr. Ernst's office or mine. You just
   have to read it, check it for accuracy.
 4
 5
             You're going to get a separate sheet of paper
    called an errata sheet if you have changes because the
 6
 7
   court reporter made mistakes, or you or I made clear
   mistakes, you note them on a separate sheet. Okay?
 9
             You can keep the transcript for whatever it's
10
          And then you send the errata sheet back to
11
   whomever we tell you to send it to. It will be to him,
   me or the court reporter.
12
13
             MR. ERNST: Let's just stipulate -- do you want
    the original? Normally how it's done here is the
14
15
   original is sent directly to the physician; that the
   physician also has the right to waive signature if he
16
    chooses to do so.
17
18
             You have that right, just waive it. Then you
19
    don't have to read it.
20
             If you choose to read it, you may certainly do
21
          You may make changes or corrections.
22
             If you make changes or corrections, you need to
23
   put them on an errata sheet.
24
             If we can stipulate to this, this is how it's
25
   normally done here.
```

```
1
             If you send the original directly to the doctor
 2
   with a self-addressed, stamped envelope to my office, I
   will forward the original, or maintain the original and
 3
   produce it at trial without further notice or subpoena.
 4
 5
   And I will notify all parties of any changes or
   corrections.
 6
             If you would like to have it sent directly to
 7
 8
   you, that's perfectly okay.
 9
             MR. MORIARTY: I didn't follow three quarters
   of that because it sounds like prop -- some California
10
11
   proposition thing.
12
             MS. DONAHUE: It is the normal custom, perhaps,
13
    in California, but we like the original sent to us.
   Either Mr. Moriarty or my office.
14
15
                        Why don't we do this. Why don't we
             MR. ERNST:
   have the original sent to the doctor with a
16
   self-addressed, stamped envelope sent back to you,
17
18
   Alicia or Mr. Moriarty.
19
             MS. DONAHUE: Fine to me.
20
             MR. MORIARTY: Yes.
             MS. DONAHUE: Yes, me.
21
2.2
             MR. ERNST: Send it to Alicia.
23
             I would like a copy.
24
             I think that's all we need to do.
25
             You can sign under penalty of perjury.
```

```
1
             Court reporter is relieved of her duties under
 2
   the code.
 3
             Otherwise, you've got to go to her office and
   sign it.
 4
 5
             MR. MORIARTY: No, he's not going to her
   office.
 6
 7
             MR. ERNST: We mail it to him. He can sign
 8
   under penalty of perjury with a self-addressed stamped
   envelope to Alicia's office.
             You'll get the original.
10
11
             You agree, Alicia, to notify all counsel of any
    changes or corrections that this doctor makes in the
12
13
   transcript.
14
             MS. DONAHUE: We usually have him send it back
    to her, and she sends it to us.
15
16
             MR. ERNST:
                        That's fine.
17
             MS. DONAHUE: Which I think is the better way
18
    than me being under that duty.
19
             Everything is fine as long as self-addressed
20
   envelope goes to you, and you send us the original, and
21
   notify all counsel of any changes.
22
             MR. MORIARTY: I have no idea why an original
23
   transcript would go to him when actually what he's
24
   writing on is the errata sheet, and then we have to keep
25
   track of an original transcript.
```

```
1
             MR. ERNST: That's the way it's usually done.
 2
             THE REPORTER: We usually stipulate that if the
 3
    original is lost or destroyed, a certified copy can be
    used in lieu.
 5
             MS. DONAHUE: That's fine.
              (Discussion held off the record.)
 6
 7
             MR. MORIARTY: So the left half you'll mark as
 8
    Exhibit 6.
 9
              (Defendants' Exhibit 6 was marked for
10
              identification )
11
              (Deposition concluded at 12:29 p.m.)
12
13
14
15
16
17
18
19
20
21
22
23
24
25
```

```
1
    STATE OF CALIFORNIA
                                )ss.
    COUNTY OF SAN LUIS OBISPO )
 2
 3
                   WITNESS'S CERTIFICATE
 4
 5
             I, Gordon Dean Lemm, M.D., declare that the
 6
 7
    answers to the foregoing deposition are true to the best
    of my knowledge and belief.
 9
                                                  , 2009.
10
    Dated this day of
11
12
13
14
                          Gordon Dean Lemm, M.D.
15
16
17
18
19
20
21
22
23
24
25
```

```
1
   STATE OF CALIFORNIA
                                )ss.
   COUNTY OF SAN LUIS OBISPO
 2
 3
                     REPORTER'S CERTIFICATE
 4
 5
 6
             I, Cindy D. Griffith, a Certified Shorthand
 7
    Reporter in and for the State of California, do hereby
 8
    certify:
 9
             That, prior to being examined, the witness
   named in the foregoing proceeding was by me sworn to
10
11
    tell the truth, the whole truth and nothing but the
   truth.
12
13
             That said deposition was taken before me at the
    time and place therein set forth and was taken down by
14
15
   me in shorthand and thereafter reduced to computerized
16
    transcription.
17
             I hereby certify that the foregoing deposition
18
    is a full, true and correct transcript of my shorthand
19
   notes so taken.
20
             Dated at San Luis Obispo, California, this 12th
   day of October, 2009.
21
2.2
2.3
                             CINDY D. GRIFFITH
24
                             CERTIFIED SHORTHAND REPORTER
25
```